UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

RANDIE GREEN,
Plaintiff,

vs.

MEDTRONIC, INC., and MEDTRONIC, USA, INC., a Minnesota Corporation,
Defendant.

FILED: JULY 21, 2008
08CV4137
JUDGE LINDBERG
MAGISTRATE JUDGE BROWN

TC

COMPLAINT

NOW COMES the Plaintiff, RANDIE GREEN, ("Plaintiff"), by and through his attorneys, THE LAW GROUP, LTD., and complaining of the Defendant, MEDTRONIC, INC. and MEDTRONIC, USA, INC., ("Hereinafter referred to collectively as Defendants), states as follows:

I. PARTIES

A. PLAINTIFF

1. Plaintiff, RANDIE GREEN, is a citizen and resident of the state of Illinois.

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2. Plaintiff was implanted with a Medtronic implantable defibrillator, Model Number 7232C, on or about December 1, 2003 as a result of Plaintiff's diagnosis of heart failure. The Medtronic implantable defibrillator was alleged to maintain an appropriate cardiac rhythm in Plaintiff's heart in order to prevent sudden cardiac arrest.

3. Upon learning from a news report that the Medtronic implantable defibrillator that was implanted in Plaintiff may fail to function and result in his possible death, Plaintiff had the device removed and replaced on or about March 8, 2005.

B. DEFENDANT

4. Defendant, MEDTRONIC, INC, is a Minnesota Corporation with its principal place of business located at 710 Medtronic Parkway, Minneapolis, Minnesota.

5. Defendant, MEDTRONIC USA, INC., is a Minnesota Corporation with its principle place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432-5604.

6. MEDTRONIC, INC., and MEDTRONIC USA, INC., are biomedical engineering company, whose core products include but are not limited to Cardiac Rhythm Disease Management products, Neuromodulation, Spinal, and

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ENT Surgery products and CardioVascular products, including the Medtronic implantable defibrillator, Model Number 7232CX.

7. At all times relevant hereto, Defendants, MEDTRONIC, INC., and MEDTRONIC USA, INC., were engaged in the business of designing, licensing, manufacturing, providing labeling, selling, marketing, distributing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, medical devices known as an implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy defibrillators (CRT-D), under the brand names of InSync III Protect, In Sync I/II/III Marquis, Marquis VD/DR and Maximo VR/DR (hereinafter referred to collectively as the "Devices").

II. JURISDICTION

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because this is an action by an individual Plaintiff and Defendant who are each citizens of a different state.

9. Both MEDTRONIC, INC., and MEDTRONIC USA, INC. are corporations headquartered in and residents of the State of Minnesota. Defendants have, therefore, subjected themselves to personal jurisdiction and venue is proper in this District pursuant to 28 U.S.C. § 1391.

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10. The Plaintiff, RANDIE GREEN, is a citizen and resident of the State of Illinois.

11. On July 19, 2007, Plaintiff and Defendant, Medtronic, Inc., filed a Joint Stipulation of Voluntary Dismissal Without Prejudice pursuant to Rule 41(a)(1)(I) of the Federal Rule of Civil Procedure from the United States District Court, District of Minnesota. The Dismissal Order was entered on July 30, 2007.

III. FACTUAL ALLEGATIONS

12. The devices, manufactured by Defendants, are surgically installed inside the body.

13. The ICD devices provides automatic detection of ventricular arrhythmias and delivery of user-selected therapies, in the form of a shock, for the detected arrhythmia. The ICD is implanted in patients who suffer from a rapid, life-threatening heart rhythm disturbance which could result in sudden cardiac arrest without the use of the ICD device.

14. The CRT-D devices provide electrical impulses to the heart in the event of heart failure symptoms.

15. Both the ICD and CRT-D devices are operated by a battery that is contained within the implanted device.

16. The FDA Premarket approval for battery charges to the Maximo VR Model 7232 was approved on October 6, 2003.

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17. On or about April 2001 to December 2003, Defendants placed defective batteries resulting in rapid battery depletion in the ICD and CRT-D devices.

18. In February of 2005, Defendants disclosed to physicians and to the Food and Drug Administration the existence of the defective battery issue which caused rapid battery depletion due to a specific internal battery short mechanism. The rapid battery depletion caused a complete loss of device function within a few hours to a few days.

19. At all times relevant to this action, Defendants knew and/or had reason to know that the devices were not safe for Plaintiff's use and could result in physical trauma, injury and/or death.

20. Plaintiff failed to possess knowledge of the device's defect that was implanted in Plaintiff's body until reviewing a news report on or about February 2005.

21. The FDA has published evidence of documented injuries of heart attacks, death, as well as other injuries necessitating life threatening required intervention for those persons who were implanted with defective devices.

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COUNT 1
VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1 et seq.

22. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

23. At all times relevant to this action, the Illinois Consumer Fraud and Deceptive Business Practices Act codified at 815 ILCS 505/1 et. seq, was in effect.

24. Section 2 of the Illinois Consumer Fraud Act, 815 ILCS 505/2, states that:

> "Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use of employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5(a) of the Federal Trade Commission Act." 815 ILCS 505/2 (815 ILCS 505/2).

25. Defendant has engaged in deceptive acts or practices, in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act (815 ILCS 505/1-505/12, including, but not limited to utilizing deception, fraud, misrepresentation, concealment, omission and suppression of research from

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investigations, adverse events reported to the U.S. Food and Drug Administration (FDA) and clinical trials regarding the safety, efficacy, and the unreasonably dangerous nature of the risk of heart attacks, strokes, sudden cardiac death and other complications resulting from the defective batteries found within the defibrillator/pacemaker.

26. Defendant violated the Illinois Consumer Fraud and Deceptive Business Practices Act by concealing, omitting and failing to inform Plaintiff and other purchasers of the safety concerns present in defibrillator/pacemaker that Plaintiff relied upon when he had the defibrillator implanted on December 1, 2003.

27. Defendants' deceptive acts/conduct occurred during a course of conduct involving trade or commerce.

28. As a direct and proximate result of Defendants' violations of the Illinois Consumer Fraud and Deceptive Business Practices Act, Plaintiff was deceived and such deception caused Plaintiff to suffer physical injuries and consequently suffer compensatory to be proven at trial.

COUNT II
STRICT LIABILITY PURSUANT TO §402A OF THE RESTATEMENT (SECOND) OF TORTS

29. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

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30. Defendants, from their headquarters in Minnesota, made every and all decisions regarding the manufacturing, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing the implantable defibrillator model 7232CX in the United States, which it sold and distributed throughout the United States to the doctors which implanted the device into Plaintiff's body.

31. Plaintiff was implanted with the defibrillator without making any changes or alterations to the defibrillator.

32. The defibrillator sold to Plaintiff reached the Plaintiff without substantial change in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned, and otherwise distributed.

33. The Plaintiff was not aware of, and reasonably could not have discovered, the dangerous nature of the product until well after Plaintif's use and subsequent injuries requiring hospitalization.

34. At the time the defibrillator/pacemaker was manufactured and sold to Plaintiff by Defendants, it was defective in design and unreasonably dangerous, subjecting users to risks of heart attacks, strokes and other illnesses.

35. As a direct and proximate result of Defendants' decision making process, related to the manufacturing, creating, designing, testing, labeling,

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sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing the defective defibrillator/pacemaker, Plaintiff suffered injuries requiring hospitalization and consequently suffered compensatory and punitive damages in an amount to be proven at trial.

36. Defendants, therefore, are strictly liable to Plaintiff. Additionally, Defendants' conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the safety of users of the defibrillator/pacemaker. The Plaintiff, therefore, is entitled to punitive damages.

COUNT II
NEGLIGENCE

37. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

38. It was the duty of the Defendants to use reasonable care and/or comply with the federal requirements regarding the marketing, selling, advertising, design, warning, and otherwise distributing the Medtronic defibrillator/pacemaker Model Number 7232.

39. Contrary to their duty, Defendants' are guilty of one or more of the following careless and negligent acts and/or omissions:

(A). Failed to adequately and properly test and inspect the implanted defibrillator/pacemaker Model Number 7232 so as to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured and sold;

(B). Failed to utilize and/or implement a reasonably safe design in the manufacture of the defibrillator/pacemaker Model

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Number 7232 subjecting users to risks of heart attacks, death, and other illnesses;

(C). Failed to manufacture the defibrillator/pacemaker Model Number 7232 in a reasonably safe condition for which it was intended;

(D). Failed to adequately and properly warn users and physicians of the risks of battery depletion when used in a manner for which it was intended;

(E). Failed to adequately and properly label the defibrillator/pacemaker Model Number 7232 so as to warn the Plaintiff of the defective battery risks;

(F). Failed to adequately and properly provide Plaintiff with post-marketing warning or instructions for the use of the defibrillator/pacemaker Model Number 7232

(G). Manufactured the defibrillator/pacemaker Model Number 7232 that was implanted into Plaintiff, which constituted a hazard to Plaintiff's health;

(H). Manufactured defibrillator/pacemaker Model Number 7232 which caused adverse side effects

(I). Failed to conduct sufficient testing which, if properly performed, would have shown that the defibrillator/pacemaker had a serious battery defect causing heart attacks, death and other serious side effects upon its depletion

(J). Were otherwise careless and negligent.

40. As a direct and proximate result of Defendants' marketing, selling, advertising, and otherwise distributing the defibrillator/pacemaker Model Number 7232, Plaintiff suffered compensatory and punitive damages in an amount to be proven at trial.

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COUNT V
NEGLIGENCE PER SE

41. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

42. Defendants had an obligation not to violate the Premarket Approval (PMA) Regulations pursuant to the Medical Device Amendments codified at 21 U.S.C. §360, et seq.;§360(e)(1)(A-D); 21 C.F.R. § 801.1 and 801.6 and 21 CFR §814.39(d)(1) and (2) as well as the specific PMA Order Number P980016 regulations approved on October 9, 1998 and corresponding Supplement Number S038 for battery changes to the Chi 4420L Battery dated October 23, 2003, in the manufacture, design, formulation, compounding, testing, production, processing, assembly, inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale and warning of the risks and dangers of the defibrillator/pacemaker.

43. Plaintiff, as a purchaser and consumer of the implantable defibrillator/pacemaker, is within the class of persons the statutes and regulations described above are designed to protect and Plaintiff's injury is of the type of harm these statutes are designed to prevent and therefore Defendants' are subject to civil liability for all damages arising therefrom, under theories of negligence per se.

44. Defendants' failed to meet the standard of care set by the following statutes and regulations, which were intended for the benefit of individuals such as the Plaintiff, making Defendants' negligent per se:

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(A) The labeling lacked adequate information on the use of the defibrillator/pacemaker[21 C.F.R. Section 801.1; 801.5; 801.109; P980016};

(B) The labeling failed to provide adequate warnings that the defibrillator/pacemaker carried a risk of death or permanent disability as soon as there was reasonable evidence of their association with the product [21 C.F.R. Section 801.4; 801.5; 801.109; P980016 and corresponding supplements];

(C) There was inadequate information for patients for the safe and effective use of Defendants' product [21 C.F.R. Section 801.5; 801.109; P980016];

(D) There was inadequate information and/or directions regarding special care to be exercised by the doctor for safe and effective use of Defendants' product [21 C.F.R. 801.5; 801.109; P980016]; and

(E) The labeling was misleading and promotional [21 C.F.R. 801.6; P980016].

45. As a result of the violations of the statutes described above, Plaintiff suffered injuries and damages as alleged herein.

COUNT VI
BREACH OF EXPRESS WARRANTY

46. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

47. Defendants expressly warranted to Plaintiff, by and through statements made by Defendants or their authorized agents, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the defibrillator/pacemaker implanted in Plaintiff was safe, effective, fit and proper for its intended use.

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48. In using the defibrillator/pacemaker, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of Defendants. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended.

49. As a direct and proximate result of Defendants breach of warranty, Plaintiff suffered serious injury and as a result has suffered compensatory and punitive damages in an amount to be proven at trial.

COUNT VII
BREACH OF IMPLIED WARRANTY

50. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

51. Prior to the time that the defibrillator/pacemaker was implanted in Plaintiff, Defendants impliedly warranted to Plaintiff that the defibrillator/pacemaker was of merchantable quality and safe and fit for the use for which it was intended.

52. Plaintiff was and is unskilled in the research, design and manufacture of the defibrillator/pacemaker and reasonably relied entirely on the skill, judgment and implied warranty of Defendants.

53. The defibrillator/pacemaker was dangerous and defective and therefore not safe for its intended use nor of merchantable quality, as warranted by Defendants, in that it had dangerous propensities when put to its intended use and caused severe injuries to Plaintiff.

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54. As a direct and proximate result of Defendants' breaches of warranties, Plaintiff suffered compensatory and punitive damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, RANDIE GREEN, by and through his attorneys, THE LAW GROUP, LTD., prays for relief as follows:

1. For general damages in a sum in excess of the jurisdictional minimum of this Court;
2. Medical, incidental, hospital and service expenses according to proof;
3. Loss of earnings and earning capacity according to proof;
4. Prejudgment and post judgment interest as provided by law;
5. Compensatory damages in excess of the jurisdictional minimum of the Court, according to proof;
6. Consequential damages in excess of the jurisdictional minimum of the Court, according to proof;
7. Punitive and exemplary damages;
8. Attorneys' fees, expenses and costs of this action; and
9. Such further relief as this Court deems necessary, just and proper.

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

RESPECTFULLY SUBMITTED,

By: /s/ Kurt D. Hyzy
Kurt D. Hyzy, #6196871
Pamela G. Sotoodeh, #6284622
Lynn M. Herbstman, #6286390
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